

Application No.: 09/055,818 Docket No.: BAKER 3.0-002 CIP CIP CIP J

IN THE CLAIMS

1-177 cancelled

178. (previously presented) A pharmaceutical composition for oral administration to a mammalian subject, comprising:

a) a taxane or taxane derivative as active ingredient; and

b) a vehicle comprising i) at least about 30% by weight of a carrier comprising Vitamin E TPGS; and ii) a co-solubilizer comprising ethanol and propylene glycol, or ethanol and a lower molecular weight polyethylene glycol (PEG).

179. (previously presented) The composition of claim 178, wherein said co-solubilizer comprises ethanol and propylene glycol.

180. (previously presented) The composition of claim 178, wherein said vehicle comprises about 30-90% by weight of Vitamin E TPGS.

181. (previously presented) The composition of claim 178, wherein said taxane is dissolved or dispersed in said vehicle.

182. (currently amended) The composition of claim 178, wherein said taxane ~~in~~is present in said vehicle in a concentration of about 2-500 mg/ml or mg/g.

183. (previously presented) The composition of claim 182, wherein the concentration of said taxane in said vehicle is about 2-50 mg/ml or mg/g.

184. (previously presented) The composition of claim 178, wherein said vehicle comprises about 0 to 70% by weight of said co-solubilizer.

185. (previously presented) The composition of claim 178, wherein said vehicle comprises about 10-50% by weight of said co-solubilizer.

Application No.: 09/055,818 Docket No.: BAKER 3.0-002 CIP CIP CIP 1

186. (previously presented) The composition of claim 178, wherein said co-solubilizer comprises ethanol and said lower molecular weight PEG.

187. (previously presented) The composition of claim 186, wherein said lower molecular weight PEG comprises PEG 200 or PEG 400.

188. (previously presented) The composition of claim 187, wherein said lower molecular weight PEG comprises PEG 400.

189. (previously presented) The composition of claim 178, wherein said taxane is docetaxel.

190. (previously presented) The composition of claim 178, wherein said taxane is paclitaxel.

191. (previously presented) The composition of claim 190, wherein said co-solubilizer comprises ethanol and propylene glycol.

192. (previously presented) The composition of claim 191, wherein said co-solubilizer is present in an amount of 50% to 70% by weight of said vehicle.

193. (previously presented) The composition of claim 190, which is in a liquid oral dosage form.

194. (previously presented) The composition of claim 190, wherein said co-solubilizer comprises ethanol and a lower molecular weight polyethylene glycol (PEG).

195. (previously presented) The composition of claim 194, wherein said co-solubilizer is present in an amount of about 10-50% by weight of said vehicle.

196. (previously presented) The composition of claim 194, wherein said lower molecular weight PEG is PEG 400.

197. (previously presented) The composition of claim 194, which is in an oral dosage form of a soft or hard gelatin capsule.

Application No.: 09/055,818 Docket No.: BAKER 3.0-002 CIP CIP CIP 1

198. (previously presented) The composition of claim 178, further comprising a pharmaceutical excipient, diluent, sweetener, flavoring agent or coloring agent.

199. (previously presented) The composition of claim 178, further comprising a sweetener, flavoring agent or coloring agent.

200. (currently amended) The composition of claim 178, which is in an oral dosage form that contains about 20-1,000 mg/m² of said taxane based on the body surface of the mammalian subject.

201. (currently amended) The composition of claim 178, which is in an oral dosage form that contains about 50-200 mg/m² of said taxane based on the body surface of the mammalian subject.

202. (currently amended) The composition of claim 178, which is in an oral dosage form that contains about 0.5-30 mg/kg of said taxane based on the weight of the mammalian subject.

203. (currently amended) The composition of claim 178, which is in an oral dosage form that contains about 2-6 mg/kg of said taxane based on the weight of the mammalian subject.

204. (previously presented) A pharmaceutical composition for oral administration to a mammalian subject, comprising:

a taxane or taxane derivative as active ingredient;

a vehicle comprising i) at least about 30% by weight of a carrier comprising Vitamin E TPGS, and ii) a co-solubilizer comprising ethanol in an amount of about 10-50 % by weight of said vehicle; wherein said composition is in an oral dosage form of a hard or soft gelatin capsule.

205. (previously presented) The composition of claim 204, wherein said taxane is docetaxel.

206. (previously presented) The composition of claim 204, wherein said taxane is paclitaxel.

Application No.: 09/055,818 Docket No.: BAKER 3.0-002 CIP CIP CIP 1

207. (previously presented) A pharmaceutical composition for oral administration to a mammalian subject, comprising:

a taxane or taxane derivative as active ingredient;
a vehicle comprising i) at least about 30% by weight of a carrier comprising Vitamin E TPGS, and ii) a co-solubilizer comprising propylene glycol.

208. (previously presented) The composition of claim 207, wherein said carrier is present in an amount of about 30-90% by weight of said vehicle.

209. (previously presented) The composition of claim 207, wherein propylene glycol is present in an amount of about 0 to 70% by weight of said vehicle.

210. (previously presented) The composition of claim 208, wherein propylene glycol is present in an amount of about 10-50% by weight of said vehicle.

211. (previously presented) The composition of claim 210, wherein said co-solubilizer further comprises ethanol.

212. (previously presented) The composition of claim 211, wherein said co-solubilizer is present in an amount of 50-70% by weight of said vehicle.

213. (previously presented) The composition of claim 211, which is a solution or a suspension.

214. (previously presented) The composition of claim 212, which is an oral dosage form of a liquid.

215. (previously presented) The composition of claim 207, wherein said taxane is docetaxel.

216. (previously presented) The composition of claim 207, wherein said taxane is paclitaxel.

217. (previously presented) The composition of claim 211, wherein said taxane is paclitaxel.

218. (previously presented) The composition of claim 212, wherein said taxane is paclitaxel.

219. (previously presented) The composition of claim 213,

Application No.: 09/055,818 Docket No.: BAKER 3.0-002 CIP CIP CIP I

wherein said taxane is paclitaxel.

220. (previously presented) A pharmaceutical composition for oral administration to a mammalian subject, comprising:

a) a taxane or taxane derivative as active ingredient;

b) a vehicle comprising i) at least 30% by weight of a carrier comprising Vitamin E TPGS, and ii) a co-solubilizer comprising a lower molecular weight PEG selected from the group consisting of PEG 200 and PEG 400, wherein said co-solubilizer is present in an amount of about 10-50% by weight of said vehicle.

221. (previously presented) The composition of claim 220, wherein said composition is a solution or a suspension.

222. (previously presented) The composition of claim 220, wherein said co-solubilizer further comprises ethanol.

223. (previously presented) The composition of claim 222, wherein said lower molecular weight PEG is PEG 400.

224. (previously presented) The composition of claim 220, which is in an oral dosage form of a soft or hard gelatin capsule.

225. (previously presented) The composition of claim 220, wherein said taxane is docetaxel.

226. (previously presented) The composition of claim 220, wherein said taxane is paclitaxel.

227. (previously presented) The composition of claim 222, wherein said taxane is paclitaxel.

228. (previously presented) The composition of claim 223, wherein said taxane is paclitaxel.

229. (previously presented) A pharmaceutical composition for oral administration to a mammalian subject, comprising:

a taxane or taxane derivative as active ingredient;

a vehicle comprising i) at least about 30% by weight of a carrier comprising Vitamin E TPGS, and ii) a co-

Application No.: 09/055,818 Docket No.: BAKER 3.0-002 CIP CIP CIP 1

solubilizer comprising N-methyl-2-pyrrolidone, glycerol or propylene glycol esters of caprylic and capric acids, polyethylene glycol esters of caprylic and capric acids, saturated coconut and palmkernel fatty acids, or saturated polyglycolized glycerides.

230. (previously presented) The composition of claim 229, wherein said co-solubilizer comprises N-methyl-2-pyrrolidone.

231. (previously presented) The composition of claim 229, wherein said co-solubilizer comprises glycerol or propylene glycol esters of caprylic and capric acids.

232. (previously presented) The composition of claim 231, wherein said glycerol or propylene glycol esters of caprylic and capric acids comprise PEG-6-caprylic/capric glycerides.

233. (previously presented) The composition of claim 229, wherein said co-solubilizer comprises polyethylene glycol esters of caprylic and capric acids.

234. (previously presented) The composition of claim 229, wherein said co-solubilizer comprises saturated coconut and palm kernel fatty acids.

235. (previously presented) The composition of claim 234, wherein said saturated coconut and palm kernel fatty acids comprise saturated coconut and palm kernel C8-C10 fatty acids.

236. (previously presented) The composition of claim 229, wherein said co-solubilizer comprises saturated polyglycolized glycerides.

237. (previously presented) The composition of claim 236, wherein said saturated polyglycolized glycerides comprise glycerides of C8-C18 fatty acids.

238. (previously presented) The composition of claim 229, wherein said co-solubilizer further comprises ethanol.

239. (previously presented) The composition of claim 229, wherein said co-solubilizer is present in an amount of about 10-50% by weight of said vehicle.

Application No.: 09/055,818 Docket No.: BAKER 3.0-002 CIP CIP CIP 1

240. (previously presented) The composition of claim 229, wherein said taxane is docetaxel.

241. (previously presented) The composition of claim 229, wherein said taxane is paclitaxel.

242. (previously presented) The composition of claim 237, wherein said taxane is paclitaxel.

243. (previously presented) The composition of claim 238, wherein said taxane is paclitaxel.

244. (previously presented) A method of treating a mammalian subject suffering from a taxane-responsive disease condition, comprising the oral administration to the subject of a pharmaceutical composition, comprising:

a) a taxane or taxane derivative as active ingredient; and

b) a vehicle comprising i) at least about 30% by weight of a carrier comprising Vitamin E TPGS; and ii) a co-solubilizer comprising ethanol and propylene glycol, or ethanol and a lower molecular weight polyethylene glycol (PEG).

245. (previously presented) The method of claim 244, wherein the co-solubilizer comprises ethanol and propylene glycol.

246. (previously presented) The method of claim 244, wherein the vehicle comprises about 30-90% by weight of Vitamin E TPGS.

247. (previously presented) The method of claim 244, wherein the taxane is dissolved or dispersed in the vehicle.

248. (previously presented) The method of claim 244, wherein the concentration of the taxane in the vehicle is about 2-500 mg/ml or mg/g.

249. (previously presented) The method of claim 248, wherein the concentration of the taxane in the vehicle is about 2-50 mg/ml or mg/g.

Application No.: 09/055,818 Docket No.: BAKER 3.0-002 CIP CIP CIP]

250. (previously presented) The method of claim 244, wherein the vehicle comprises about 0 to 70% by weight of the co-solubilizer.

251. (previously presented) The method of claim 244, wherein the vehicle comprises about 10-50% by weight of the co-solubilizer.

252. (previously presented) The method of claim 244, wherein the co-solubilizer comprises ethanol and the lower molecular weight PEG.

253. (previously presented) The method of claim 252, wherein the lower molecular weight PEG comprises PEG 200 or PEG 400.

254. (previously presented) The method of claim 253, wherein the lower molecular weight PEG comprises PEG 400.

255. (previously presented) The method of claim 244, wherein the taxane is docetaxel.

256. (previously presented) The method of claim 244, wherein the taxane is paclitaxel.

257. (previously presented) The method of claim 256, wherein the co-solubilizer comprises ethanol and propylene glycol.

258. (previously presented) The method of claim 257, wherein the co-solubilizer is present in an amount of 50% to 70% by weight of the vehicle.

259. (previously presented) The method of claim 256, wherein the composition is in a liquid oral dosage form.

260. (previously presented) The method of claim 256, wherein the co-solubilizer comprises ethanol and a lower molecular weight polyethylene glycol (PEG).

261. (previously presented) The method of claim 260, wherein the co-solubilizer is present in an amount of about 10-50% by weight of the vehicle.

Application No.: 09/055,818 Docket No.: BAKER 3.0-002 CIP CIP CIP 1

262. (previously presented) The method of claim 260, wherein the lower molecular weight PEG is PEG 400.

263. (previously presented) The method of claim 260, wherein the composition is in an oral dosage form of a soft or hard gelatin capsule.

264. (previously presented) The method of claim 244, wherein the composition further comprises a pharmaceutical excipient, diluent, sweetener, flavoring agent or coloring agent.

265. (previously presented) The method of claim 244, wherein the composition further comprises a sweetener, flavoring agent or coloring agent.

266. (currently amended) The method of claim 244, wherein the composition is in an oral dosage form that contains about 20-1,000 mg/m² of the taxane based on the body surface of the mammalian subject.

267. (currently amended) The method of claim 244, wherein the composition is in an oral dosage form that contains about 50-200 mg/m² of the taxane based on the body surface of the mammalian subject.

268. (currently amended) The method of claim 244, wherein the composition is in an oral dosage form that contains about 0.5-30 mg/kg of the taxane based on the weight of the mammalian subject.

269. (currently amended) The method of claim 244, wherein the composition is in an oral dosage form that contains about 2-6 mg/kg of the taxane based on the weight of the mammalian subject.

270. (previously presented) A method of treating a mammalian subject suffering from a taxane-responsive disease condition, comprising the oral administration to the subject of a pharmaceutical composition, comprising:

a taxane or taxane derivative as active ingredient;

Application No.: 09/055,818 Docket No.: BAKER 3.0-002 CIP CIP CIP 1

a vehicle comprising i) at least about 30% by weight of a carrier comprising Vitamin E TPGS, and ii) a co-solubilizer comprising ethanol in an amount of about 10-50 % by weight of said vehicle.

271. (previously presented) The method of claim 270, wherein the taxane is docetaxel.

272. (previously presented) The method of claim 270, wherein the taxane is paclitaxel.

273. (previously presented) A method of treating a mammalian subject suffering from a taxane-responsive disease condition, comprising the oral administration to the subject of a pharmaceutical composition, comprising:

a taxane or taxane derivative as active ingredient;

a vehicle comprising i) at least about 30% by weight of a carrier comprising Vitamin E TPGS, and ii) a co-solubilizer comprising propylene glycol.

274. (previously presented) The method of claim 273, wherein the carrier is present in an amount of about 30-90% by weight of the vehicle.

275. (previously presented) The method of claim 273, wherein the propylene glycol is present in an amount of about 0 to 70% by weight of the vehicle.

276. (previously presented) The method of claim 274, wherein the propylene glycol is present in an amount of about 10-50% by weight of the vehicle.

277. (previously presented) The method of claim 276, wherein the co-solubilizer further comprises ethanol.

278. (previously presented) The method of claim 277, wherein the co-solubilizer is present in an amount of 50-70% by weight of the vehicle.

279. (previously presented) The method of claim 277, wherein the composition is a solution or a suspension.

280. (previously presented) The method of claim 278,

Application No.: 09/055,818 Docket No.: BAKER 3.0-002 CIP CIP CIP 1

wherein the composition is in an oral dosage form of a liquid.

281. (previously presented) The method of claim 273, wherein the taxane is docetaxel.

282. (previously presented) The method of claim 273, wherein the taxane is paclitaxel.

283. (previously presented) The method of claim 277, wherein the taxane is paclitaxel.

284. (previously presented) The method of claim 278, wherein the taxane is paclitaxel.

285. (previously presented) The method of claim 279, wherein the taxane is paclitaxel.

286. (previously presented) A method of treating a mammalian subject suffering from a taxane-responsive disease condition, comprising the oral administration to the subject of a pharmaceutical composition, comprising:

a) a taxane or taxane derivative as active ingredient;

b) a vehicle comprising i) at least 30% by weight of a carrier comprising Vitamin E TPGS, and ii) a co-solubilizer comprising a lower molecular weight PEG selected from the group consisting of PEG 200 and PEG 400, wherein said co-solubilizer is present in an amount of about 10-50% by weight of the vehicle.

287. (previously presented) The method of claim 286, wherein the composition is a solution or a suspension.

288. (previously presented) The method of claim 286, wherein the co-solubilizer further comprises ethanol.

289. (previously presented) The method of claim 288, wherein the lower molecular weight PEG is PEG 400.

290. (previously presented) The method of claim 286, wherein the composition is in an oral dosage form of a soft or hard gelatin capsule.

291. (previously presented) The method of claim 286,

Application No.: 09/055,818 Docket No.: BAKER 3.0-002 CIP CIP CIP 1

wherein the taxane is docetaxel.

292. (previously presented) The method of claim 286, wherein the taxane is paclitaxel.

293. (previously presented) The method of claim 288, wherein the taxane is paclitaxel.

294. (previously presented) The method of claim 289, wherein the taxane is paclitaxel.

295. (previously presented) A method of treating a mammalian subject suffering from a taxane-responsive disease condition, comprising the oral administration to the subject of a pharmaceutical composition, comprising:

a taxane or taxane derivative as active ingredient;

a vehicle comprising i) at least about 30% by weight of a carrier comprising Vitamin E TPGS, and ii) a co-solubilizer comprising N-methyl-2-pyrrolidone, glycerol or propylene glycol esters of caprylic and capric acids, polyethylene glycol esters of caprylic and capric acids, saturated coconut and palm kernel fatty acids, or saturated polyglycolized glycerides.

296. (previously presented) The method of claim 295, wherein the co-solubilizer comprises N-methyl-2-pyrrolidone.

297. (previously presented) The method of claim 295, wherein the co-solubilizer comprises glycerol or propylene glycol esters of caprylic and capric acids.

298. (previously presented) The method of claim 297, wherein the glycerol or propylene glycol esters of caprylic and capric acids comprise PEG-6-caprylic/capric glycerides.

299. (previously presented) The method of claim 295, wherein the co-solubilizer comprises polyethylene glycol esters of caprylic and capric acids.

300. (previously presented) The method of claim 295, wherein the co-solubilizer comprises saturated coconut and palm kernel fatty acids.

Application No.: 09/055,818 Docket No.: BAKER 3.0-002 CIP CIP CIP 1

301. (previously presented) The method of claim 300, wherein the saturated coconut and palm kernel fatty acids comprise saturated coconut and palmkernel C8-C10 fatty acids.

302. (previously presented) The method of claim 295, wherein the co-solubilizer comprises saturated polyglycolized glycerides.

303. (previously presented) The method of claim 302, wherein the saturated polyglycolized glycerides comprise glycerides of C8-C18 fatty acids.

304. (previously presented) The method of claim 295, wherein the co-solubilizer further comprises ethanol.

305. (previously presented) The method of claim 295, wherein the co-solubilizer is present in an amount of about 10-50% by weight of said vehicle.

306. (previously presented) The method of claim 295, wherein the taxane is docetaxel.

307. (previously presented) The method of claim 295, wherein the taxane is paclitaxel.

308. (previously presented) The method of claim 303, wherein the taxane is paclitaxel.

309. (previously presented) The method of claim 304, wherein the taxane is paclitaxel.

310. (previously presented) The method of any one of claims 244, 270, 273, 283, 286 and 295, further comprising the oral co-administration to the subject of an effective bioavailability-enhancing amount of an oral bioavailability enhancing agent.

311. (previously presented) The method of claim 310, wherein the effective amount of the enhancing agent is about 0.1-20 mg/kg based on the weight of the mammalian subject.

312. (previously presented) The method of claim 310, wherein the enhancing agent is administered either:

a) about 0.5-72 hours before;

Application No.: 09/055,818 Docket No.: BAKER 3.0-002 CIP CIP CIP]

b) less than 0.5 hours before, together with or less than 0.5 hours after, or

c) both about 0.5-72 hours before and again less than 0.5 hours before, together with or less than 0.5 hours after administration of the composition comprising the taxane.

313. (previously presented) The method of claim 312, wherein said enhancing agent is administered one hour before the administration of the composition.

314. (previously presented) The method of claim 310, wherein the enhancing agent is a cyclosporin.

315. (previously presented) The method of claim 314, wherein the cyclosporin is cyclosporin A.

316. (previously presented) The method of claim 314, wherein the cyclosporin is selected from the group consisting of cyclosporins A-Z, (Me-Ile-4)-cyclosporin, dihydro cyclosporin A, dihydro cyclosporin C, and acetyl cyclosporin A.

317. (previously presented) The method of claim 314, wherein said cyclosporin is selected from the group consisting of cyclosporin A, cyclosporin C, cyclosporin D, cyclosporin F, dihydro cyclosporin A, dihydro cyclosporin C, and acetyl cyclosporin A.

318. (previously presented) The method of claim 310, wherein the disease condition is selected from the group consisting of cancers, tumors, malignancies, uncontrolled tissue or cellular proliferation secondary to tissue injury, polycystic kidney disease, inflammatory diseases and malaria.

319. (previously presented) The method of claim 310, wherein the disease condition is a cancer selected from the group consisting of hepatocellular carcinoma, liver metastases, cancers of the gastrointestinal tract, pancreas, prostate and lung, and Kaposi's sarcoma.

Application No.: 09/055,818 Docket No.: BAKER 3.0-002 CIP CIP CIP]

320. (previously presented) The method of claim 310, wherein the enhancing agent is orally administered in a separate oral dosage form.

321. (previously presented) The method of claim 244, wherein the subject is a human.

322. (previously presented) The method of claim 270, wherein the subject is a human.

323. (previously presented) The method of claim 273, wherein the subject is a human.

324. (previously presented) The method of claim 283, wherein the subject is a human.

325. (previously presented) The method of claim 286, wherein the subject is a human.

326. (previously presented) The method of claim 295, wherein the subject is a human.

327. (previously presented) The method of claim 310, wherein the subject is a human.

328. (previously presented) The method of claim 303, wherein the co-solubilizer further comprises ethanol.

329. (previously presented) The method of claim 270, wherein said composition is in an oral dosage form of a hard or soft gelatin capsule.

330. (previously presented) The composition of claim 237, wherein said co-solubilizer further comprises ethanol.

331. (previously presented) The method of claim 314, wherein the taxane is paclitaxel.

332. (previously presented) The method of claim 331, wherein the subject is a human.

333. (previously presented) The method of claim 314, wherein the taxane is docetaxel.

334. (previously presented) The method of claim 333, wherein the subject is a human.

335. (previously presented) The method of claim 315,

Application No.: 09/055,818 Docket No.: BAKER 3.0-002 CIP CIP CIP 1

wherein the taxane is paclitaxel.

336. (previously presented) The method of claim 335,
wherein the subject is a human.

337. (previously presented) The method of claim 315,
wherein the taxane is docetaxel.

338. (previously presented) The method of claim 337,
wherein the subject is a human.